

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

OCT 08 2002

Applicant: ~~JOHN~~ COYLE et al.

Serial No.: 09/613,591

Group Art Unit No.: 1647 TECH CENTER 1600/2900

Filed: July 10, 2000

Examiner: R. Deberry

For: COMBINATION THERAPY FOR CONDITIONS  
LEADING TO BONE LOSS

Docket No.: A-378CIP5

**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE  
PATENTING REJECTION OVER A PENDING APPLICATION**

Assistant Commissioner For Patents  
Washington, D.C. 20231

Sir:

Petitioner, Amgen Inc., is the owner of the entire interest in the instant application.

Petitioner hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from Patent No. 6,288,032, and hereby agrees that any patent so granted on said above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to any patent issuing from Patent No. 6,288,032, this agreement to run with any patent granted on said above-identified application and to be binding upon the grantee, its successors, or assigns.

Petitioner does not disclaim any terminal part of any patent granted on said above-identified application that would extend to the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from Patent No. 6,288,032 in the event that any said patent issuing from Patent No. 6,288,032 later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321(a), has all claims canceled by a reexamination certificate, is reissued, or is otherwise terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

Copies of the assignment documents in the chain of title from the original owner to assignee are attached, and were recorded in the Patent and Trademark Office at reel 011607 and frame 0444.

The undersigned has reviewed the attached assignment documents and certifies that, to the best of the undersigned's knowledge and belief, title is in the assignee identified above.

**EXPRESS MAIL CERTIFICATE**

"Express Mail" mail labeling number: EL360691385US

Date of Deposit: October 2, 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 39 C.F.R. 1.10 on the date indicated above and is addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231.

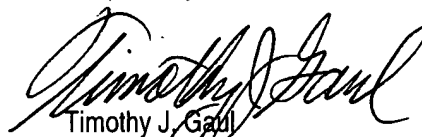
Lynne Buchsbaum  
Printed Name

Lynne Buchsbaum  
Signature

09/613591  
10/10/2002 STRAHEL 00000007 010519  
01 7C:148  
110.00 CH

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

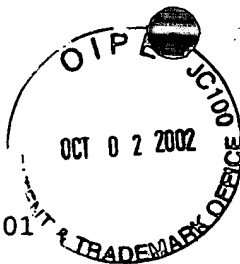
Respectfully submitted,

A handwritten signature in black ink, appearing to read "Timothy J. Gaul". The signature is fluid and cursive, with the first name "Timothy" being more prominent.

Timothy J. Gaul  
Attorney for Applicants  
Registration No.: 33,111  
Phone: (805) 447-2688  
Date: October 2, 2002

Please send all future correspondence to:

US Patent Operations/ [TJG]  
Dept. 4300, M/S 27-4-A  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799



LE → TJG  
UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

MAY 29, 2001

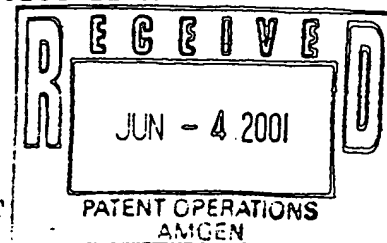
PTAS



\*101647117A\*

AMGEN INC.  
U.S. PATENT OPERATIONS/TJG  
DEPT. 4300, M/S 27-4-A  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS, CA 91320-1799

UNITED STATES PATENT AND TRADEMARK OFFICE  
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT



THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 03/06/2001

REEL/FRAME: 011607/0444  
NUMBER OF PAGES: 13

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

BOYLE, WILLIAM J.

DOC DATE: 10/03/2000

ASSIGNOR:

LACEY, DAVID LEE

DOC DATE: 10/03/2000

ASSIGNOR:

CALZONE, FRANK J.

DOC DATE: 10/03/2000

ASSIGNOR:

CHANG, MING-SHI

DOC DATE: 10/16/2000

ASSIGNOR:

SENALDI, GIORGIO

DOC DATE: 10/03/2000

ASSIGNEE:

AMGEN INC.  
DEPT. 4300, M/S 27-4-A  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS, CALIFORNIA  
91320-  
1799

011607/0444 PAGE 2

SERIAL NUMBER: 09613591  
PATENT NUMBER:

FILING DATE: 07/10/2000  
ISSUE DATE:

PEARLENE FOSTER, PARALEGAL  
ASSIGNMENT DIVISION  
OFFICE OF PUBLIC RECORDS

D \$

03-26-2001

Revised Form PTO-1595  
(Rev. 6-93)

3.6.01



FEET

U.S. Department of Commerce  
Patent and Trademark Office

Docket No.: A-378CIP5

101647117

To the Honorable Commissioner of Patents and Trademarks, attached original documents or copy thereof.

1. Name of conveying party(ies):  
William J. Boyle, David Lee Lacey, Frank J. Calzone,  
Ming-Shi Chang, Giorgio Senaldi

2. Name and address of receiving party(ies):  
Name: Amgen Inc.

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

Internal Address: Dept. 4300, M/S 27-4-A

3. Nature of conveyance:

- ☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Other \_\_\_\_\_

Street Address: One Amgen Center Drive

City: Thousand Oaks State: CA Zip: 91320-1799

Execution Date: October 16, 2000

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):  
If this document is being filed together with a new application, the execution date of the application is: \_\_\_\_\_

A. Patent Application No.(s)  
09/613,591

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: U.S. Patent Operations/ TJG

Internal Address: Dept. 4300, M/S 27-4-A

AMGEN INC.

Street Address: One Amgen Center Drive

City: Thousand Oaks State: CA Zip: 91320-1799

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41) .....\$ 40.00

- ☐ Enclosed  
☒ Authorized to be charged to deposit account.

8. Deposit account number: 01-0519

☒ The Commissioner is hereby authorized to charge any additional filing fees which may be required or credit any overpayment to Deposit Account No. 01-0519

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Timothy J. Gaul  
Name of Person Signing

Timothy J. Gaul 2/28/01  
Signature Date

Total number of pages including cover sheet, attachments, and document: 13

09/613,591 09/613,591 09/613,591 09/613,591  
40.00 CH

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

February 28, 2001  
Date

Christina A. Huetten  
Signature

# ASSIGNMENT

Whereas, I, William J. Boyle, 11678 Chestnut Ridge Street, Moorpark, California 93021

David Lee Lacey, 614 Paseo Vista, Newbury Park, California 91320

Frank J. Calzone, 841 Pine Crest Circle, Westlake Village, California 91361

Ming-Shi Chang, 3<sup>rd</sup> Floor, No. 58, Tong-Ning Road, Tainan, Taiwan

Giorgio Senaldi, 2846 White Ridge Place, Thousand Oaks, California 91362

have made an invention which is the subject of an application for Letters Patent of the United States ("Application") entitled

## COMBINATION THERAPY FOR CONDITIONS LEADING TO BONE LOSS

which is found in:

- ☐ (a) the U.S. Patent Application executed on even date herewith;
- ☐ (b) the U.S. Patent Application executed on \_\_\_\_\_
- ☒ (c) U.S. Application Serial No.: 09/613,591 filed on July 10, 2000
- ☐ (d) U.S. Patent No.: \_\_\_\_\_

Whereas AMGEN INC., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 wishes to acquire the entire interest in all inventions disclosed in such Application:

Now, therefore, in consideration of the sum of one dollar (\$1.00) and other good and valuable consideration, the receipt of which is hereby acknowledged, I hereby sell, assign, transfer and set over unto AMGEN INC., its successors and assigns (collectively "AMGEN") my entire right, title and interest in, to and under the Application, and any provisional application(s) from which Application is derived, and all priority rights to which the Application may be entitled, including all priority rights for other countries arising therefrom, all inventions therein disclosed, and any and all Letters Patent of the United States and of all other countries which may be granted for such inventions, or any of them, including divisional, continuation, and/or continuation-in-part applications based on the above-identified Application, all such inventions and all rights in such Application and Letters Patent to be held and enjoyed by AMGEN for its own use and enjoyment to the full end of the term or terms for which such Letters Patent may be granted, as fully and entirely as the same would have been held and enjoyed by me had this assignment and sale not been made.

Further, I hereby sell, assign, transfer, and set over unto AMGEN my entire right, title and interest in or to the right to refer to, to access, and to control microorganism(s) or other biological material(s) related to the Application and which are deposited by me or at my direction or deposited on my behalf by Amgen, its affiliates, employees or employees of its affiliates. The transfer of such right, title and interest includes, without limitation, my unreserved and irrevocable consent and authorization to AMGEN to refer to the deposited microorganisms(s) or other biological materials(s) in the Application and the right to make available to the public the deposited material in accordance with the laws, treaties, statutes, rules, regulations and the like of the United States, all other countries, and any patent granting authority or organization.

I authorize and request the Commissioner of Patents and Trademarks of the United States to issue any such Letters Patent which may be granted on the Application to AMGEN as assignee of the entire right, title and interest therein and thereto.

For myself and for my legal representatives, I covenant and agree with AMGEN that I have not granted to any others any license to make, use or sell any such inventions, that my right, title and interest in such inventions has not been encumbered, that I have good right and title to sell and assign the same, and that I will not execute any instrument in conflict herewith.

For myself and for my heirs, successors and legal representatives, I further covenant and agree with AMGEN that upon request I and they will: (i) execute continuing, divisional, or reissue applications, amended specifications, or rightful declarations or oaths; (ii) communicate to AMGEN any facts known to me or them relating to such inventions or the history thereof; (iii) execute preliminary statements and testify in any interference proceedings or litigation; (iv) execute and deliver any application papers, assignments, or other instruments; and (v) do all other acts which, in the opinion of counsel for AMGEN, may be necessary or desirable to secure the grant of Letters Patent to AMGEN or its nominees, in the United States and in all other countries where AMGEN may desire to have such inventions, or any of them, patented, with specifications and claims in such form as shall be approved by counsel for AMGEN and to vest and confirm in AMGEN or its nominees the full and complete legal and equitable title to all such Letters Patent, without further consideration than that now paid but at the expense of AMGEN.

In Witness Whereof I have executed this assignment on the 03 day of OCTOBER 2000.

William J. Boyle  
(Name of Inventor)

William J. Boyle  
(Signature of Inventor)

### UNITED STATES OF AMERICA

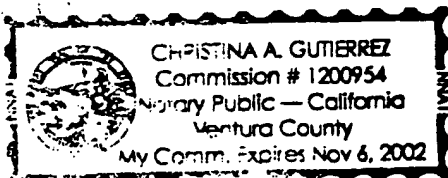
State of California }  
County of Ventura } ss:

October 3 2000

Before me, a Notary Public for Ventura County, State of California, personally appeared  
William J. Boyle

☒ personally known to me - OR - ☐ proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he/she executed the same in his/her authorized capacity, and that by his/her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.



Christina A. Gutierrez  
Notary Public

My commission expires

November 6, 2002

In Witness Whereof I have executed this assignment on the 3 day of October 20 00

David Lee Lacey  
(Name of Inventor)

[Signature]  
(Signature of Inventor)

# UNITED STATES OF AMERICA

State of California } ss:  
County of Ventura }

October 3 20 00

Before me, a Notary Public for Ventura County, State of California, personally appeared  
David Lee Lacey

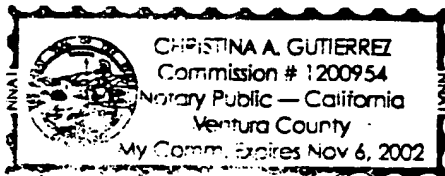
☒ personally known to me - OR - ☐ proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he/~~she~~ executed the same in his/~~her~~ authorized capacity, and that by his/~~her~~ signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Christina A. Gutierrez  
Notary Public

My commission expires

November 6 2002





In Witness Whereof I have executed this assignment on the 3 day of October 20 00

Frank J. Calzone  
(Name of Inventor)

Frank J. Calzone  
(Signature of Inventor)

## UNITED STATES OF AMERICA

State of California } ss:  
County of Ventura }

October 3 20 00

Before me, a Notary Public for Ventura County, State of California, personally appeared  
Frank J. Calzone

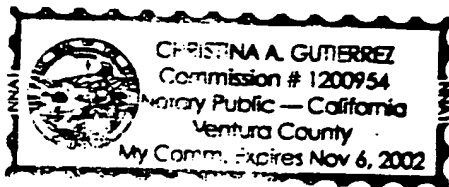
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WITNESS my hand and official seal.

Christina A. Gutierrez  
Notary Public

My commission expires

November 6 2002



In Witness Whereof I have executed this assignment on the \_\_\_\_\_ day of \_\_\_\_\_ 20 00

Ming-Shi Chang

(Name of Inventor)

\_\_\_\_\_  
(Signature of Inventor)

**UNITED STATES OF AMERICA**

State of  
County of

} ss:

\_\_\_\_\_  
20 00

Before me, a Notary Public for

County, State of

, personally appeared

Ming-Shi Chang

☐ personally known to me - OR - ☐ proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he/she executed the same in his/her authorized capacity, and that by his/her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

\_\_\_\_\_  
Notary Public

My commission expires  
\_\_\_\_\_

In Witness Whereof I have executed this assignment on the 3 day of October 20 00

Giorgio Senaldi  
(Name of Inventor)

Giorgio Senaldi  
(Signature of Inventor)

**UNITED STATES OF AMERICA**

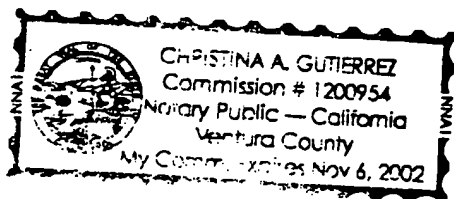
State of California } ss:  
County of Ventura }

October 3 20 00

Before me, a Notary Public for Ventura County, State of California, personally appeared  
Giorgio Senaldi

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Christina A. Gutierrez  
Notary Public

My commission expires

November 6 2002

# ASSIGNMENT

Whereas, I, William J. Boyle, 11678 Chestnut Ridge Street, Moorpark, California 93021  
David Lee Lacey, 614 Paseo Vista, Newbury Park, California 91320  
Frank J. Calzone, 841 Pine Crest Circle, Westlake Village, California 91361  
Ming-Shi Chang, 3<sup>rd</sup> Floor, No. 58, Tong-Ning Road, Tainan, Taiwan  
Giorgio Senaldi, 2846 White Ridge Place, Thousand Oaks, California 91362

have made an invention which is the subject of an application for Letters Patent of the United States ("Application") entitled

## COMBINATION THERAPY FOR CONDITIONS LEADING TO BONE LOSS

which is found in:

- ☐ (a) the U.S. Patent Application executed on even date herewith;
- ☐ (b) the U.S. Patent Application executed on \_\_\_\_\_
- ☒ (c) U.S. Application Serial No.: 09/613,591 filed on July 10, 2000
- ☐ (d) U.S. Patent No.: \_\_\_\_\_

Whereas AMGEN INC., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 wishes to acquire the entire interest in all inventions disclosed in such Application:

Now, therefore, in consideration of the sum of one dollar (\$1.00) and other good and valuable consideration, the receipt of which is hereby acknowledged, I hereby sell, assign, transfer and set over unto AMGEN INC., its successors and assigns (collectively "AMGEN") my entire right, title and interest in, to and under the Application, and any provisional application(s) from which Application is derived, and all priority rights to which the Application may be entitled, including all priority rights for other countries arising therefrom, all inventions therein disclosed, and any and all Letters Patent of the United States and of all other countries which may be granted for such inventions, or any of them, including divisional, continuation, and/or continuation-in-part applications based on the above-identified Application, all such inventions and all rights in such Application and Letters Patent to be held and enjoyed by AMGEN for its own use and enjoyment to the full end of the term or terms for which such Letters Patent may be granted, as fully and entirely as the same would have been held and enjoyed by me had this assignment and sale not been made.

Further, I hereby sell, assign, transfer, and set over unto AMGEN my entire right, title and interest in or to the right to refer to, to access, and to control microorganism(s) or other biological material(s) related to the Application and which are deposited by me or at my direction or deposited on my behalf by Amgen, its affiliates, employees or employees of its affiliates. The transfer of such right, title and interest includes, without limitation, my unreserved and irrevocable consent and authorization to AMGEN to refer to the deposited microorganisms(s) or other biological materials(s) in the Application and the right to make available to the public the deposited material in accordance with the laws, treaties, statutes, rules, regulations and the like of the United States, all other countries, and any patent granting authority or organization.

I authorize and request the Commissioner of Patents and Trademarks of the United States to issue any such Letters Patent which may be granted on the Application to AMGEN as assignee of the entire right, title and interest therein and thereto.

For myself and for my legal representatives, I covenant and agree with AMGEN that I have not granted to any others any license to make, use or sell any such inventions, that my right, title and interest in such inventions has not been encumbered, that I have good right and title to sell and assign the same, and that I will not execute any instrument in conflict herewith.

For myself and for my heirs, successors and legal representatives, I further covenant and agree with AMGEN that upon request I and they will: (i) execute continuing, divisional, or reissue applications, amended specifications, or rightful declarations or oaths; (ii) communicate to AMGEN any facts known to me or them relating to such inventions or the history thereof; (iii) execute preliminary statements and testify in any interference proceedings or litigation; (iv) execute and deliver any application papers, assignments, or other instruments; and (v) do all other acts which, in the opinion of counsel for AMGEN, may be necessary or desirable to secure the grant of Letters Patent to AMGEN or its nominees, in the United States and in all other countries where AMGEN may desire to have such inventions, or any of them, patented, with specifications and claims in such form as shall be approved by counsel for AMGEN and to vest and confirm in AMGEN or its nominees the full and complete legal and equitable title to all such Letters Patent, without further consideration than that now paid but at the expense of AMGEN.

In Witness Whereof I have executed this assignment on the 03 day of OCTOBER 2000.

William J. Boyle  
(Name of Inventor)

William J. Boyle  
(Signature of Inventor)

# UNITED STATES OF AMERICA

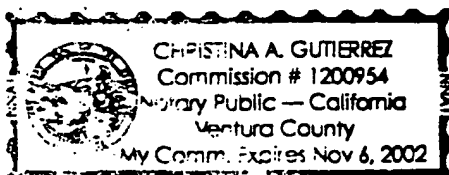
State of California }  
County of Ventura } ss:

October 3 2000

Before me, a Notary Public for Ventura County, State of California, personally appeared  
William J. Boyle

☒ personally known to me - OR - ☐ proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he/~~she~~ executed the same in his/~~her~~ authorized capacity, and that by his/~~her~~ signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.



Christina A. Gutierrez  
Notary Public

My commission expires

November 6, 2002

In Witness Whereof I have executed this assignment on the 3 day of October 20 00

David Lee Lacey  
(Name of Inventor)

[Signature]  
(Signature of Inventor)

**UNITED STATES OF AMERICA**

State of California } ss:  
County of Ventura }

October 3 20 00

Before me, a Notary Public for Ventura County, State of California, personally appeared  
David Lee Lacey

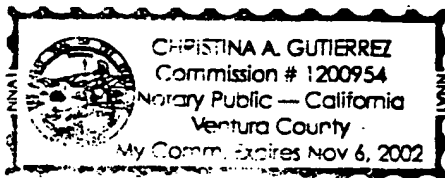
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WITNESS my hand and official seal.

Christina A. Gutierrez  
Notary Public

My commission expires

November 6 20 02



In Witness Whereof I have executed this assignment on the 3 day of October 20 00

Frank J. Calzone  
(Name of Inventor)

Frank J. Calzone  
(Signature of Inventor)

**UNITED STATES OF AMERICA**

State of California } ss:  
County of Ventura }

October 3 20 00

Before me, a Notary Public for Ventura County, State of California, personally appeared

Frank J. Calzone

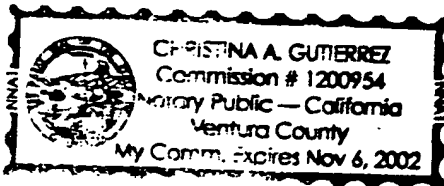
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WITNESS my hand and official seal.

Christina A. Gutierrez  
Notary Public

My commission expires

November 6 2002



In Witness Whereof I have executed this assignment on the 16<sup>th</sup> day of October 2000

Ming-Shi Chang  
(Name of Inventor)

Ming-Shi Chang  
(Signature of Inventor)

State of Taiwan )  
City of Keelung )  
County of American Institute in Taiwan ) ss  
Keelung Branch Office )

UNITED STATES OF AMERICA

16 OCT 2000 20 00

Before me, a Notary Public for

County, State of , personally appeared

Ming-Shi Chang

☐ personally known to me - OR - ☒

proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he/she executed the same in his/her authorized capacity, and that by his/her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

David W. Seckler  
Notary Public

My commission expires

David W. Seckler

Special Notary (PL96-8)

Duly appointed and qualified

My Commission expires: August 15, 2003



In Witness Whereof I have executed this assignment on the 3 day of October 20 00

Giorgio Senaldi  
(Name of Inventor)

Giorgio Senaldi  
(Signature of Inventor)

# UNITED STATES OF AMERICA

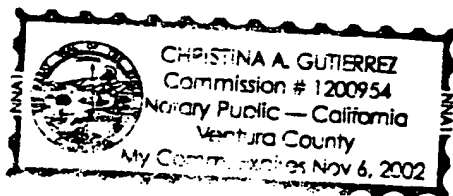
State of California }  
County of Ventura } ss:

October 3 20 00

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Giorgio Senaldi

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Christina A. Gutierrez  
Notary Public

My commission expires

November 6 2002